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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/753,669  | 01/08/2004  | Donald C. Roe        | 7537CQ              | 1141             |
| 27752 7590 07/08/2010<br>THE PROCTER & GAMBLE COMPANY<br>Global Legal Department - IP<br>Sycamore Building - 4th Floor<br>299 East Sixth Street<br>CINCINNATI, OH 45202 |             |                      |                     |                  |
| EXAMINER<br>STEPHENS, JACQUELINE F  |             |                      |                     |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 3761  |             |                      |                     |                  |
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| 07/08/2010  |             | PAPER                |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/753,669

**Applicant(s)**

ROE ET AL.

**Examiner**

Jacqueline F. Stephens

**Art Unit**

3761

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3-7, 9-11, 15-41, 43-45 and 47-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-7, 9-11, 15-41, 43-45, 47-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed 7/1/10 have been fully considered but are not persuasive. Applicant repeats the argument that Everhart does not teach or suggest a biosensor having the characteristics recited by the independent claims; specifically a biosensor including at least one biologically reactive bio-recognition element comprising a biologically derived material and adapted to interact selectively with a specific microorganism selected from the group of pathogenic bacteria, colonic bacteria, viruses, parasites, and fungi. However, as previously argued by the Examiner, Everhart teaches a biosensor capable of detecting – bacteria (col. 11, lines 1-6) and pathological disorder (col. 3, lines 12-15; claim 8); specific microorganisms (Table 2). Everhart further teaches the biosensor includes at least one bio-recognition element comprising a biologically derived material as discussed below. Additionally, Everhart teaches the chemical reactive means provides a visual signal of detection of the one or more pathogenic microorganisms (Abstract, col. 3 lines 53-57). Therefore, the rejection under Everhart and Al-Sabah is maintained.

### ***Claim Rejections - 35 USC § 103***

2 The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 3-7, 9-11, 15-19, 21-25, 36-39, and 40, 41, 43-45, and 47-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Everhart et al. USPN 5468236.

As to claims 1, 3-7, 9, 10 and 40, 41, 43-45, and 47, Everhart teaches a disposable absorbent article comprising a sensor for detecting analytes in bodily waste or on a user's skin. Everhart discloses a disposable article comprising a topsheet **14**, a backsheet **12**, and an absorbent core **16** as claimed ('236 Figure 2). Everhart disclose the target analyte may include a health or nutritional marker ('236 col. 3, lines 10-29), which may be an enzyme, endogenous secretion, proteinaceous matter, or microorganism (col. 3, lines 56-65). Everhart generally teaches a chemically reactive means (biosensor) that reacts with a substance present in bodily excrement. Everhart teaches the chemically reactive means includes at least one bio-recognition element

comprising a biologically derived material in that Everhart teaches an example of the chemically reactive means having GOD (Glucose oxidase), POD (peroxidase), and TMB (tetramethylbenzidine) for placement in an infant diaper (col. 8, lines 19-32). Glucose oxidase is an enzyme that is commonly used in biosensors as taught in Hijikihigawa et al. USPN 5140393. The chemical reactive means provides a visual signal of detection of a specific microorganism (Abstract, col. 3 lines 53-57). Everhart teaches a chemically reactive substance acting upon mammalian bodily excrement that provides the types of substance present and an estimate of the concentration of the substance (Everhart col. 3, lines 21-29). Everhart teaches a biosensor capable of detecting – bacteria (col. 11, line s1-6) and pathological disorder (col. 3, lines 12-15; claim 8); specific microorganisms (Table 2).

Regarding claim 11, the invention of Everhart provides a visual indication of a substance upon reacting with body excrement. Body excrement, particularly perspiration, may not necessarily provide clinically observable symptoms, such as a skin rash. In this manner, the invention of Everhart would provide information to the wearer prior to clinically visible symptoms.

Regarding claims 15-19, the sensor provides a signal to the wearer, caregiver, or an actuator ('236 Abstract) as broadly as claimed.

Regarding claims 21 and 23, the sensor is affixed to a substrate ('236, col. 6, lines 4-6).

Regarding claims 22 and 24, the sensor is detachable from the article ('236 col. 6, lines 26-32).

Regarding claims 25 and 48, the sensor may adhere to a wearer's skin ('236, Abstract).

Regarding claims 36-39 and 49-52, Everhart describes a biosensor for detecting a target analyte upon excretion of bodily fluids or waste materials. Everhart provides a response within a period of time that stays valid until the article is discarded. The response factor would have been obvious by optimizing the type of biosensor materials since the invention of Everhart is used in the same environment and problem that is solved is the same as the claimed invention. Moreover, discovering optimum values only involves routine skill in the art, *In re Boesch*, 617 F. 2d 272, 205 FUSPQ 215 (CCPA 1980).

6. Claims 28-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Everhart et al. USPN 5468236 in view of Al-Sabah USPN 5868723.

As to claims 28-31, Everhart disclose the present invention substantially as claimed. However, Everhart fail to disclose the disposable article has an actuator. Al-Sabah discloses an absorbent article comprising an actuator 43, which comprises a power source 42(Figure 7). The actuator performs a responsive function when the

sensor detects an input (Abstract). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate an actuator as taught in Al-Sabah to the sensor apparatus of Everhart. Doing so would provide a means for alerting the user or a health care professional of the presence of the target analyte.

As to claims 32 and 33, Everhart/Al-Sabah teaches a receiver integral with the article (Al-Sabah col. 5, lines 35-37).

As to claim 34 and 35, Everhart/Al-Sabah teaches a transmitter (Al-Sabah col. 5, lines 1-4).

### ***Conclusion***

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline F. Stephens whose telephone number is (571) 272-4937. The examiner can normally be reached on Monday-Friday 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jacqueline F Stephens/  
Primary Examiner, Art Unit 3761